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09/685,940	10/10/2000	Shi Kun Huang	5325-0166.30	6690

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

	Application No. 09/685,940	Applicant(s) Huang
	Examiner Gollamudi Kishore	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 6, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-33 is/are pending in the application.

4a) Of the above, claim(s) 19-27 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-18 and 28-33 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4 and 5

6) Other:

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DETAILED ACTION

1. **Applicant's election with traverse of Group I in Paper No. 9 is acknowledged.** The traversal is on the ground(s) that there is no serious burden on the examiner. This is not found persuasive because as shown by the examiner, the classification of the groups is different. Liposome come under the class 424 and this search is not necessary for the compound claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 1-18 and 28-33.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claims 1-18 and 28-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

It is unclear from the claims whether the lipid of the formula forms bilayer by itself or said lipid is part of the composition. Clarification is requested.

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Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. Claims 1-3, 5-15, and 28-33 are rejected under 35 U.S.C. 102(e) as being anticipated by Wolff (5,965,434) of record.

Wolf discloses liposomal compositions containing instant compounds where L is an ester and Z is either imidazole or an amino group. The liposomes carry either polypeptides or nucleic acids for transfection. The liposomes further include targeting ligand (note the abstract, columns 5-19 and claims).

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Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-15, and 28-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above.

In Wolff, 'n' is 1; however, instant compounds where n is more than 1 (claims recite 1-20) are homologues and it would have been obvious to one of ordinary skill in the art to prepare liposomes containing compounds where n is more than one since homologues are expected to behave the same way.

8. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Allen 96,056,973).

The teachings of Wolff have been discussed above. What is lacking in Wolff are the teachings of FGF as the targeting ligand.

Allen while disclosing liposomal compositions containing therapeutic agents, teaches that liposomes can be targeted to tumor cells by inclusion of targeting ligands such as FGF (note the abstract, col. 11, lines 45-53).

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The inclusion of targeting ligand such as FGF in the liposomal compositions of Wolff would have been obvious to one of ordinary skill in the art since with such an inclusion, one could target tumor cells as taught by Allen.

9. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff cited above, further in view of Zalipsky (5,395,619) of record.

Wolff does not teach the inclusion of a lipid derivatized with PEG.

Zalipsky while disclosing liposome formulations teaches that inclusion of a polymer-lipid conjugate will extend the circulation time of the liposome by several fold (note the abstract and col. 8, lines 45-53).

The inclusion of a polymer-lipid conjugate in the liposomes of Wolff would have been obvious to one of ordinary skill in the art since such an inclusion would extend the circulation time of the liposomes as taught by Zalipsky.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *T.K. Page*, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 1, 2002